REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks pursuant to and consistent with 37 C.F.R. § 1.112 are respectfully requested.

By the foregoing amendments, Claims 2, 18, and 19 were amended to omit the phrase "chiral analog." By the foregoing amendments, Claims 17, 20, and 21 were amended to omit the word "derivative." Claims 15-17 were amended to depend from Claim 2. Claims 1, 3, and 11 were canceled without prejudice or disclaimer. No new matter has been added.

Turning now to the Official Action, Claims 7 and 8 are objected to under 37 C.F.R. § 1.75(c) as purportedly being in improper dependent form for failing further limit the subject matter of a previous Claim. *See Office Action, Page 2.* According to the Examiner, the PPAR receptor activator in Claims 7-8 is an inherent property of the compositions cited therein. Applicants respectfully traverse this objection.

Claims "are but different definitions of the same disclosed subject matter, varying in breadth or scope of definition." *See M.P.E.P. § 806.03.* Accordingly, Applicants are entitled to claim alternatively or more definitely. "The fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish in inherency of that result or characteristic." *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). In the present case, the compounds administered in Claim 1 or Claim 2 *may*

comprise a PPAR receptor activator. As indicated above, this is not sufficient to establish inherency.

Applicants maintain that Claims 7 and 8 further limit the subject matter of a previous claim. Accordingly, Applicants respectfully request withdrawal of the objections to Claims 7 and 8.

Next, Claims 1-21 were rejected under 35 U.S.C. § 112, first paragraph, as purportedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention. Specifically, according to the Examiner, "the specification, while being enabling for those particular compounds disclosed in the compounds disclosed in the specification (see, e.g., page 9 of the specification herein) [ ], does not reasonably provide enablement for the employment [of] any 'chiral analogs' and 'derivatives.'" These rejections are respectfully traversed.

However, to expedite prosecution in the instant application, and not to acquiesce in the Examiner's rejections, Applicants have amended Claims 2 and 17-21 to omit reference to "chiral analogs" and "derivatives."

In light of these amendments, Applicants believe the Examiner's rejection of Claims 1-21 under 35 U.S.C. § 112, first paragraph, have been rendered moot. Accordingly, Applicants respectfully request that the rejections to Claims 2-21 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Next, Claims 1-21 were rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, according to the Examiner, the expression "regime or regimen" renders Claims 1-17 indefinite because it is not defined in the specification. In addition, the Examiner states that Claims 1-17 are indefinite due to the expression "such period of time...the desired response" in Claims 1-2. The trademark of "PPAR" allegedly renders indefinite Claims 7-8. Claims 9-12 are allegedly indefinite due to the expression "compound (1) comprising at least one linear or branch alkyl radical." Finally, the expressions "chiral analog," "derivative," "agent for combating free radicals," and "ion channel blocker" purportedly render Claims 1-21 indefinite. These rejections are respectfully traversed.

Definiteness of claim language must be analyzed, not in a vacuum, but in light of the content of the application disclosure, the teachings of the prior art, and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. *See M.P.E.P § 2171.* Using this framework, Applicants maintain that Claims 2-21 do not violate 35 U.S.C. § 112, second paragraph.

1. Regime or Regimen

Applicants maintain that "regime or regimen" is readily understood by those of skill in the art. Regime is a generic course of therapy, *e.g.*, treating inflammation with X. Regimen implies more than one treatment, *e.g.*, treating inflammation with X twice a day.

Guided by the content of the application and the teachings of the prior art, one of skill would readily appreciate that "regime or regimen," as used in Claims 2-17, relates to regulating the metabolism of cutaneous lipids, comprising topically applying at least one compound of formula (I) onto the skin. *See, for example, Paragraph 0004 of the Specification* ("The present invention also relates to a cosmetic/pharmaceutical **regime or regimen** for restoring the barrier function of the skin and more particularly for regulating the metabolism of cutaneous lipids, **comprising topically applying at least one compound of formula (I) below**, more particularly as activator of receptors of PPAR type, **onto the skin**."). Moreover, "regime or regimen" occurs in many issued U.S. Patents. *See, for example, U.S. Patent No. 6,380,263 to Pruche et al. and U.S. Patent No. 6,344, 461 to Breton et al.*

In light of the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, rejections to Claims 2-17 based on "regime or regimen."

2. "Such Period of time...the desired response"

Applicants maintain that "such period of time" and "the desired response" are readily understood by those of skill in the art. First, the "desired response" is the treatment of disorders of the barrier function of human skin, disorders of the secretion of epidermal lipids, photodermatoses or ulcers, and/or disorders of the metabolism of lipids *(See Claim 2)*. Second, the claimed compounds are administered for "such period of time" as is needed to bring about the treatment of cutaneous disorders or of the barrier function of human skin, as discussed above.

Reading the claims as a whole and in view of the application, those of skill in the art would understand the import of "such period of time ... the desired response." Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, rejections to Claims 2-17 based on "such period of time ... the desired response."

3. "PPAR"

Contrary to the Examiner's understanding, "PPAR" is *not* a trademark. Instead, by the term "PPAR" is meant a type of receptor which belongs to the family of steroid nuclear receptors. *See Paragraph 0016 of the Specification.* "By the term 'activator of receptors of PPAR type' is intended any compound that exhibits in a transactivation test, such as described in Kliewer et al., Nature, 358, 771-774 (1992), an AC_{50} of less than or equal to 10 μM. The activator of receptors of PPAR type preferably exhibits an AC_{50} of less than or equal to 2 μM and advantageously of less than or equal to 1 μM." *See Paragraph 0017 of the Specification.*

Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, rejections to Claims 7-8 based on the purported trademark "PPAR."

4. "Compound (1) comprising at least one linear..."

Claims 9-12 in the instant application specify that the compounds must comprise at least one "lower alkyl radical," "linear or branched alkyl radical," "monohydroxyalkyl radical," or "polyhydroxyalkyl radical." All four of these terms are defined in the Specification — at Paragraphs 0009, 0010, 0011, and 0012, respectively.

While several positions are available for these radials to occupy, "[b]readth of a claim is not to be equated with indefiniteness." *In re Miller*, 441 F.2d 689 (C.C.P.A. 1971). One of skill in the art would readily recognize what is meant by the claim terms and would readily appreciate the positions available to the radials. Thus, the tenets of 35 U.S.C. § 112, second paragraph, are met.

Applicants respectfully request withdrawal of the 35 U.S.C. §112, second paragraph, rejections to Claims 9-12.

5. "Chiral analog"

By the foregoing amendment, Claims 2, 18, and 19 have been amended to omit the phrase "chiral analog." In light of these amendments, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, rejection to Claims 2, 18, and 19 based on "chiral analog."

6. "Derivative"

By the foregoing amendment, Claims 17, 20, and 21 have been amended to omit the word "derivative." In light of these amendments, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, rejection to Claims 17, 20, and 21 based on "derivative."

7. "Agent for combating free radicals"

Claims 17, 20, and 21 contain the phrase "agent for combating free radicals." Free radicals are universally understood as molecular fragments having one or more unpaired electrons. This understanding is confirmed by the appearance of the phrase "free radicals"

in the claims of 437 U.S. Patents that issued between 1996 and 2002. An "agent for combating free radicals" is just that. Again, breadth of a claim is not to be equated with indefiniteness.

Because one of skill in the art readily understands "agent for combating free radicals," Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, rejections of Claims 17, 20 and 21.

8. "Ion channel blocker"

Claims 17, 20, and 21 contain the phrase "ion channel blocker." Similar to the preceding rejection term, "ion channel blocker" also enjoys universal recognition. Ions are atoms or radicals that have lost or gained one or more electrons and thus have acquired an electric charge. Ions move across membranes in what are known as channels. Thus, an "ion channel blocker" is an agent that hinders ion movement.

Because one of skill in the art readily understands "ion channel blocker," Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, rejections of Claims 17, 20, and 21.

Finally, Claims 1-21 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,763,487 to Bernardon et al. ("Bernardon"). These rejections are respectfully traversed.

To anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed. Cir. 1984).

Applicants maintain that Bernardon does not contain all elements of Claims 2-21. Bernardon does not disclose treating disorders of the barrier function of human skin, disorders of the secretion of epidermal lipids, photodermatoses or ulcers, or disorders of the metabolism lipids. Instead, Bernardon states that "compounds according to the invention display marked activity in the fields of cell differentiation and cell proliferation, and are particularly useful in the ... treatment of dermatological conditions associated with a keritinization disorder." *See Bernardon Column 1, Lines 17-24.*

Because Bernardon does not contain all elements of Claims 2-21, Applicants maintain that the test for anticipation has not been met. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejections against Claims 2-21.

CONCLUSION

From the foregoing, further and favorable consideration in the form of a Notice of Allowance is respectfully requested and earnestly solicited.

In the event that there are any questions relating to this response, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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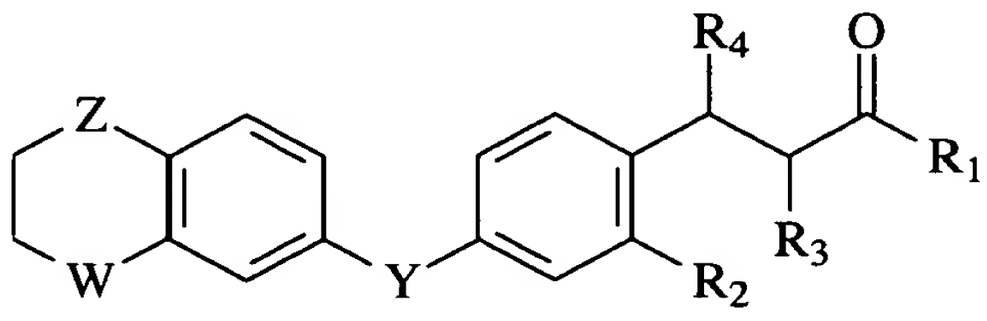
Date: July 11, 2002

Attachment to Amendment Dated July 11, 2002
Mark-up of Specification

[0002] Copending application Serial No. 09/933,835 [Attorney Docket No. 016800-452], filed concurrently herewith and assigned to the assignee hereof.

Attachment to Amendment Dated July 11, 2002
Mark-up of Claims 2 and 15-21

2. (Amended) A regime or regimen for treating disorders of the barrier function of human skin, disorders of the secretion of epidermal lipids, photodermatoses or ulcers, and/or disorders of the metabolism of lipids, comprising administering to an individual in need of such treatment, for such period of time as required to elicit the desired response, a thus-effective amount of at least one polycyclic aromatic compound having the structural formula (I):



(I)

in which R_1 is a hydrogen atom or an $-OR_5$ radical, wherein R_5 is as defined below; R_2 is a hydrogen atom or a lower alkyl radical; R_3 and R_4, which may be identical or different, are each a hydrogen atom or a lower alkyl radical, with the proviso that R_2 and R_3, may together form a naphthalene ring with the adjacent benzene ring; Y is an oxygen atom, an $S(O)_n$ radical or an $N-R_6$ radical, wherein n and R_6 are as defined below; Z and W, which may be identical or different, are each $-CR_7R_8-$, -O- or $-S(O)_m$, wherein m, R_7 and R_8 are as defined below; R_5 is a hydrogen atom, a linear or branched alkyl radical having from 1 to 20 carbon atoms, or a mono- or polyhydroxyalkyl radical; R_6 is a hydrogen atom or a lower alkyl radical; R_7 and R_8, which may be identical or different, are each a hydrogen

Attachment to Amendment Dated July 11, 2002
Mark-up of Claims 2 and 15-21

atom or a lower alkyl radical; n is 0, 1 or 2; m is 0, 1 or 2; or salt [or chiral analog] thereof.

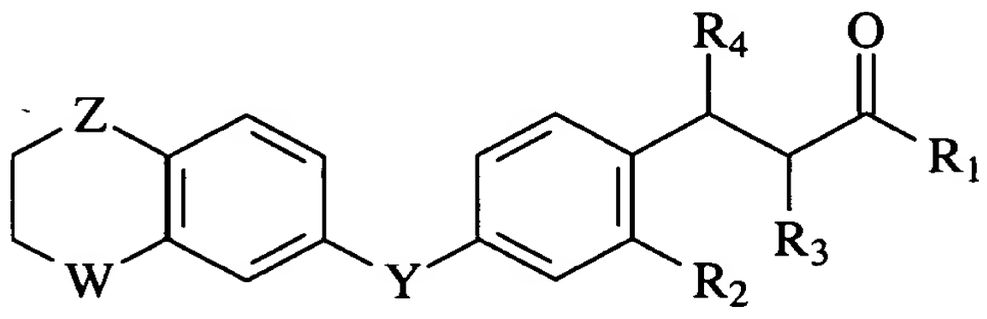
15. (Amended) The regime or regimen as defined by Claim [1] 2, comprising administering said at least one polycyclic aromatic compound (I) via enteral or parenteral route.

16. (Amended) The regime or regimen as defined by Claim [1] 2, comprising administering said at least one polycyclic aromatic compound (I) via topical or ocular route.

17. (Amended) The regime or regimen as defined by Claim [1] 2, comprising coadministering to such individual an effective amount of at least one retinoid, vitamin D, [or derivative thereof,] corticosteroid, agent for combating free radicals, α-hydroxy or α-keto acid, [or derivative thereof,] or ion channel blocker.

Attachment to Amendment Dated July 11, 2002
Mark-up of Claims 2 and 15-21

18. (Amended) Tablets, capsules, syrup, suspension, solution, powder, granules, emulsion, lipid or polymeric microspheres, nanospheres or vesicles comprising an amount effective for treating disorders of the barrier function of human skin, disorders of the secretion of epidermal lipids, photodermatoses or ulcers, and/or disorders of the metabolism of lipids, of at least one polycyclic aromatic compound having the structural formula (I):



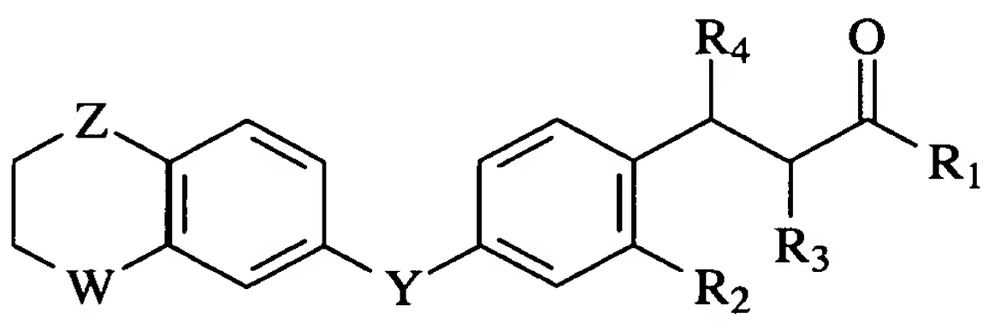
(I)

in which R_1 is a hydrogen atom or an $-OR_5$ radical, wherein R_5 is as defined below; R_2 is a hydrogen atom or a lower alkyl radical; R_3 and R_4, which may be identical or different, are each a hydrogen atom or a lower alkyl radical, with the proviso that R_2 and R_3, may together form a naphthalene ring with the adjacent benzene ring; Y is an oxygen atom, an $S(O)_n$ radical or an $N-R_6$ radical, wherein n and R_6 are as defined below; Z and W, which may be identical or different, are each $-CR_7R_8-$, -O- or $-S(O)_m$, wherein m, R_7 and R_8 are as defined below; R_5 is a hydrogen atom, a linear or branched alkyl radical having from 1 to 20 carbon atoms, or a mono- or polyhydroxyalkyl radical; R_6 is a hydrogen atom or a lower alkyl radical; R_7 and R_8, which may be identical or different, are each a hydrogen

Attachment to Amendment Dated July 11, 2002
Mark-up of Claims 2 and 15-21

atom or a lower alkyl radical; n is 0, 1 or 2; m is 0, 1 or 2, or salt [or chiral analog] thereof, formulated into an enterally/parenterally administrable, cosmetically/pharmaceutically acceptable vehicle, diluent or carrier therefor.

19. (Amended) A salve, cream, emulsion, milk, ointment, powder, impregnated pad, solution, gel, spray, lotion, suspension, lipid or polymeric microspheres, nanospheres, vesicles, patch, hydrogel, soap or shampoo comprising an amount effective for treating disorders of the barrier function of human skin, disorders of the secretion of epidermal lipids, photodermatoses or ulcers, and/or disorders of the metabolism of lipids, of at least one polycyclic aromatic compound having the structural formula (I):



(I)

in which R_1 is a hydrogen atom or an $-OR_5$ radical, wherein R_5 is as defined below; R_2 is a hydrogen atom or a lower alkyl radical; R_3 and R_4, which may be identical or different, are each a hydrogen atom or a lower alkyl radical, with the proviso that R_2 and R_3, may together form a naphthalene ring with the adjacent benzene ring; Y is an oxygen atom, an $S(O)_n$ radical or an $N-R_6$ radical, wherein n and R_6 are as defined below; Z and W, which

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Mark-up of Claims 2 and 15-21

may be identical or different, are each $-CR_7R_8-$, -O- or $-S(O)_m$, wherein m, R_7 and R_8 are as defined below; R_5 is a hydrogen atom, a linear or branched alkyl radical having from 1 to 20 carbon atoms, or a mono- or polyhydroxyalkyl radical; R_6 is a hydrogen atom or a lower alkyl radical; R_7 and R_8, which may be identical or different, are each a hydrogen atom or a lower alkyl radical; n is 0, 1 or 2; m is 0, 1 or 2, or salt [or chiral analog] thereof, formulated into a topically applicable, cosmetically/pharmaceutically acceptable vehicle, diluent or carrier therefor.

20. (Amended) The formulation as defined by Claim 18, further comprising an effective amount of at least one retinoid, vitamin D, [or derivative thereof,] corticosteroid, agent for combating free radicals, α-hydroxy or α-keto acid, [or derivative thereof,] or ion channel blocker.

21. (Amended) The formulation as defined by Claim 19, further comprising an effective amount of at least one retinoid, vitamin D, [or derivative thereof,] corticosteroid, agent for combating free radicals, α-hydroxy or α-keto acid, [or derivative thereof,] or ion channel blocker.